Patent Claims

We Claim:

1. An inhalable powder comprising 0.04 to 0.8% of tiotropium in admixture with a physiologically acceptable excipient, characterised in that the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 µm and finer excipient with an average particle size of 1 to 9 µm, the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.

2. An inhalable powder according to claim 1, characterised in that the tiotropium is present in the form of the chloride, bromide, iodide, methanesulphonate, para-toluenesulphonate or methyl sulphate thereof.

3. An inhalable powder comprising between 0.048 and 0.96% of tiotropium bromide in admixture with a physiologically acceptable excipient, characterised in that the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 µm and finer excipient with an average particle size of 1 to 9 µm, the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.

4. An inhalable powder comprising between 0.05 and 1% of tiotropium bromide monohydrate in admixture with a physiologically acceptable excipient, characterised in that the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 µm and finer excipient with an average particle size of 1 to 9 µm, the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.

5. An inhalable powder according to one of claims 1, 2, 3 or 4, characterised in that the excipient consists of a mixture of coarser excipient with an average particle size of 17 to 50 µm and finer excipient with an average particle size of 2 to 8 µm.

6. An inhalable powder according to one of claims 1, 2, 3 or 4, characterised in that the proportion of finer excipient in the total amount of excipient is 3 to 15%.

7. An inhalable powder according to one of claims 1, 2, 3 or 4, characterised in that the tiotropium used has a mean particle size of 0.5 to 10 μm.

8. An inhalable powder according to one of claims 1, 2, 3 or 4, characterised in that one or more monosaccharides, disaccharides, oligo- or polysaccharides, polyalcohols, salts thereof, or mixtures thereof are used as the excipients.

9. An inhalable powder according to claim 8, characterised in that glucose, arabinose, lactose, saccharose, maltose, dextrane, sorbitol, mannitol, xylitol, sodium chloride, calcium carbonate or mixtures thereof are used as the excipients.

10. An inhalable powder according to claim 9, characterised in that glucose or lactose or mixtures thereof are used as the excipients.

11. A process for preparing an inhalable powder according to one of claims 1 to 4, comprising: (a) mixing coarser excipient fractions with finer excipient fractions to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium.

12. An inhalable powder prepared by the process according to claim 11.

13. A method of treating a disease that is responsive to the administration of tiotropium, comprising administering to a host in need thereof an inhalable powder according to one of claims 1 to 4 or 12.

14. A method according to claim 13, wherein the disease is asthma or COPD.

15. An inhalette capsule containing an inhalable powder according to one of claims 1 to 4 or 12.

16. An inhalette capsule containing from 3 to 10 mg of inhalable powder according to one of claims 1 to 4 or 12.

17. An inhalette capsule according to claim 16, containing between 1.2 and 80 μg of tiotropium.